



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Entry and Exit Procedure for Controlled Not Classified, D-Grade, Manufacturing and Filtration-Filling Area of Large Volume Parenteral

SOP No.:		Department:	Production	
		Effective Date:		
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1.0 OBJECTIVE:

To lay down a Procedure for Entry and Exit Procedure for Controlled Not Classified, D-Grade, Manufacturing and Filtration-Filling Area of Large Volume Parenteral.

2.0 SCOPE:

This SOP is applicable for Entry and Exit Procedure for Controlled Not Classified, D-Grade, Manufacturing and Filtration-Filling Area of Large Volume Parenteral.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

DR	Door Release
COB	Cross over bench
Ltd.	Limited
QA	Quality Assurance
IPA	Iso Propyl Alcohol
SS	Stainless Steel
SOP	Standard Operating Procedure
PVT.	Private
CNC	Controlled Not Classified
DGSC	Dynamic Garment Sterile Cabinet

6.0 PROCEDURE:

6.1 ENTRY AND EXIT PROCEDURE FOR STAFF AND WORKERS:

After entrance in Plant Premises Male and Female Workers/Staff shall enter in the Concerned Area of department through separate Entry & Exit Change Room.

6.1.1 Entry procedure for CNC area:

6.1.1.1 Push the Main door of "Personnel Entry to Production area" of LVP & enter into the Common corridor.

6.1.1.2 Push the door & enter into the Male/Female Change Room-I.

6.1.1.3 Remove street Shoes/Slippers/Ornaments (Ear rings, watch, rings, bangles/Purse etc.) & kept it in the provided locker.



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6.1.1.4 Press the Interlock button & Push the door and enter into the Male or Female change Room-II.

6.1.1.5 Hand sanitized by IPA 70 % v/v.

6.1.1.6 Person who will enter in Grade-C area (Filtration, Filling & Manufacturing) will remove their street garments in common male change room II & put into dedicated garment cabinet & enter in area by following the below mentioned instruction.

6.1.1.7 Swing cross over bench to another side.

6.1.1.8 Take the factory slipper from the second side of cross over bench.

6.1.1.9 Take the primary garments from provided dress cabinet; first wear Cap followed by apron & lower.

6.1.1.10 Check the gowning in front of mirror.

6.1.1.11 Hand sanitized by IPA 70 % v/v.

6.1.1.12 Press the Interlock button & Pull the door and & enter in to common CNC corridor.

6.1.1.13 For pictorial representation follow **Annexure-I**.

6.1.2 Exit procedure for CNC area:

6.1.2.1 Press the interlock & Pull the door of concern area & enter into CNC common corridor.

6.1.2.2 Press the interlock & Push the door of second Change Room.

6.1.2.3 Remove the primary garment & kept to provided garment cabinet.

6.1.2.4 Remove factory slippers into the provided shoes rack in cross over bench & swing the cross over bench.

6.1.2.5 Wear the street garments from Dress cabinet (Only for persons who enter in the C-Area).

6.1.2.6 Sanitize the hands with 70% IPA v/v.

6.1.2.7 Press the interlock & Pull the door of Change Room-II & enter in to Primary Change Room-I.

6.1.2.8 Take Street shoes/slippers/Ornaments (Earrings, watch, rings, bangles/Purse etc.) from the lockers & wear it.

6.1.2.9 Pull the door of primary Change Room-I & enter in to common corridor of Production Area.

6.1.2.10 Pull the door of common corridor & Exit from Production area.

6.1.2.11 For pictorial representation follow **Annexure-II**.

Note: Use the CNC area emergency exit to skip away, if any type of incident happening in CNC area

6.1.3 Entry procedure for D-grade area:



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- 6.1.3.1 From the CNC common corridor before entry in primary Change Room-I, remove the factory slipper & kept in provided shoes rack.
- 6.1.3.2 Push the door & enter into the Primary Change room-I.
- 6.1.3.3 Push the door and enter into the room.
- 6.1.3.4 Push the door and enter into the Primary Change room-II.
- 6.1.3.5 Take the Self health hygiene declaration Record from the SOP stand, and enter Self health hygiene declaration details.
- 6.1.3.6 Sit on the Cross over bench.
- 6.1.3.7 Take 70% IPA v/v spray bottle and spray on both bare feet from lower and upper side. Gently rub the both feet from each other.
- 6.1.3.8 Swing cross over bench and wear D-Area slipper from second side of cross over bench.
- 6.1.3.9 Take D grade area garment, Cap and Long Apron from garment cabinet and over gown & check the outfit in mirror then sanitized hand by IPA 70% v/v and press the interlock and push the door for enter buffer air lock by pushing the door.
- 6.1.3.10 Press the interlock button & pull the door of buffer air lock & enter into D grade Area Common Corridor.
- 6.1.3.11 For pictorial representation follow **Annexure-III**.
- 6.1.4 **Exit procedure for D-grade area:**
 - 6.1.4.1 Press the interlock button & Push the door of D-grade area corridor & enter in to buffer Airlock.
 - 6.1.4.2 Press the interlock button & Pull the door of buffer Airlock & enter into Change Room-II.
 - 6.1.4.3 Remove D area garment & keep it in garment cabinet.
 - 6.1.4.4 Remove the D area slipper in to provide cross over bench.
 - 6.1.4.5 Swing cross over bench.
 - 6.1.4.6 Pull the door of Change Room-II & enter into next room.
 - 6.1.4.7 Pull the door & enter into Primary change Room-I.
 - 6.1.4.8 Pull the door & enter in the CNC corridor.
 - 6.1.4.9 Take the CNC area sleeper from shoes rack & move forward to required place.
 - 6.1.4.10 For pictorial representation follow **Annexure-IV**.



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Note: Use the D-area emergency exit to skip away, if any type of incident happening in D-area and Manufacturing Area.

6.1.5 Entry procedure for Manufacturing area:

6.1.5.1 For enter into the change room-I put the finger / thumb for scanning on affix biometrics system for authentication. After confirmation through biometrics system green light blow as well as beep sound produce. (This system allows only authorized Person entry.)

6.1.5.2 Open the door of change room-I by pushing the door with elbow and enter into change room-I.

6.1.5.3 Enter the entry time in the Entry-Exit log book (Annexure-XIV).

6.1.5.4 Remove D area slippers into the cross over bench & swing the cross over bench by press the interlocking button of personal change room- II and enter in to personal change room- II.

6.1.5.5 Sanitize the hands with 70% IPA v/v.

6.1.5.6 Open DGSC and take sterile small gloves & wear it.

6.1.5.7 Keep the Wrappers of gloves in dedicated bin.

6.1.5.8 Take the set of sterile garment Dacron bag from DSGC and first wear the head gear, boiler suit, and then booties.

6.1.5.9 Keep empty Dacron bag in dedicated bin.

6.1.5.10 Now take the sterile goggle and wear it.

6.1.5.11 Now take secondary Long/Elbow size sterile gloves and wear it.

6.1.5.12 Keep the Wrappers of gloves in dedicated bin.

6.1.5.13 Check the proper gowning in front of mirror.

6.1.5.14 Sanitize the hand with 70% IPA v/v solution.

6.1.5.15 Press the door interlocking button of manufacturing room, push the door by elbow & enter into manufacturing room.

6.1.5.16 For pictorial representation follow **Annexure-V**.

6.1.6 Exit procedure for Manufacturing area:

6.1.6.1 Press the interlock button & pull the door of manufacturing room and enter into the change room -II.

6.1.6.2 Remove the Secondary Long/Elbow size sterile gloves and keep in dedicated bin.

6.1.6.3 Press the interlock button & Pull the door of personal change room II, and enter into personal change room-I by swing the cross over bench.



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- 6.1.6.4** Remove the Sterile goggles & put in the respective place.
- 6.1.6.5** Remove sterile garment and put into dedicated bins.
- 6.1.6.6** Remove the hand gloves and put into dedicated bins.
- 6.1.6.7** Wear the D- Area Slipper from cross over bench.
- 6.1.6.8** Enter the exit time in the Entry and Exit log book.
- 6.1.6.9** For exit from change room-I put the finger /Thumb for scanning on biometrics system for authentication. After confirmation through biometrics system green light blow as well as beep sound produce.
- 6.1.6.10** Pull the door of manufacturing change room- I and enter in to D-area common corridor.
- 6.1.6.11** For pictorial representation follow **Annexure-VI**
- Note: During the running Operation in Manufacturing Area, If any of gloves gets ruptured, immediate come out from manufacturing room to Entry change room-IInd and replace it with new one , Sanitize the hands with IPA 70% v/v Solution and again, Press the door interlocking button of manufacturing room, push the door by elbow & enter into manufacturing room.*
- 6.1.7 Entry procedure for visitors in CNC area:**
- 6.1.7.1** Push the Main door of “Personnel Entry to Production area” of LVP & enter into the Common male & female corridor.
- 6.1.7.2** Push the door & enter into the Male/Female Change Room–I.
- 6.1.7.3** Press the Interlock button & Push the door and enter into the Male and Female change Room.
- 6.1.7.4** Sanitize the hands with 70% IPA v/v.
- 6.1.7.5** Sit on the cross over bench & take pair of shoes cover wear one by one & swing cross over bench.
- 6.1.7.6** Take the disposal primary garments & over gown. First wear Cap followed by apron & lower.
- 6.1.7.7** Check the gowning in front of mirror.
- 6.1.7.8** Hand sanitized by IPA 70 % v/v.
- 6.1.7.9** Press the Interlock button & Pull the door and enter in to common CNC corridor.
- 6.1.7.10** For pictorial representation follow **Annexure-VII**.
- 6.1.8 Exit procedure for visitors in CNC area :**
- 6.1.8.1** Press the interlock & Pull the door of concern area & enter into CNC common corridor.



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- 6.1.8.2** Press the interlock & Push the door of second Change Room.
- 6.1.8.3** Remove the disposal primary garment & put in respective place & cross the cross over bench.
- 6.1.8.4** Hand sanitized by IPA 70 % v/v.
- 6.1.8.5** Pull the door of Change Room-II & enter in to Primary Change Room-I.
- 6.1.8.6** Remove the Shoes Cover & put in waste bin.
- 6.1.8.7** Pull the door of primary Change Room I & enter in to common corridor of Production Area.
- 6.1.8.8** Pull the door of common corridor & Exit from Production area.
- 6.1.8.9** For pictorial representation follow **Annexure-VIII**.
- 6.1.9 Entry procedure for visitors in D-grade area:**
- 6.1.9.1** From the CNC common corridor push the door & enter into the Primary Change room-I.
- 6.1.9.2** Push the door and enter into the room.
- 6.1.9.3** Push the door and enter into the Primary Change room-II.
- 6.1.9.4** Take the Health and Hygiene Record from the SOP stand, and enter the health and hygiene details.
- 6.1.9.5** Sit on the cross over bench and take the secondary shoes cover from the tray and wear it.
- 6.1.9.6** Swing cross over bench to other side.
- 6.1.9.7** Take Disposal garment from garment cabinet and over gown (Only disposable cap - apron) & check the outfit in mirror.
- 6.1.9.8** Sanitized the hand by IPA 70 % v/v.
- 6.1.9.9** Press the interlock and enter buffer air lock by pushing the door with elbow.
- 6.1.9.10** Press the interlock button & pull the door of buffer air lock & enter into D grade Area common corridor.
- 6.1.9.11** For pictorial representation follow **Annexure-IX**.
- 6.1.10 Exit procedure for visitors in D-grade area :**
- 6.1.10.1** Press the interlock button & Push the door of D grade area corridor & enter in to buffer Airlock.
- 6.1.10.2** Press the interlock button & Pull the door of buffer Airlock & enter into Change Room- II.
- 6.1.10.3** Remove D area disposable apron & keep it in respective place.
- 6.1.10.4** Swing COB & remove secondary shoes cover and cap, Keep them in waste bin.
- 6.1.10.5** Pull the door of Change Room-II & enter into next room.
- 6.1.10.6** Pull the door & enter into Primary Change Room-I.



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6.1.10.7 Pull the door & enter the CNC common corridor.

6.1.10.8 For pictorial representation follow **Annexure-X**.

6.1.11 Entry Procedure for Filtration-Filling Area:

6.1.11.1 Record the Entry & Exit Details as per **Annexure- XIV**, Titled “**Entry - Exit Record**”.

6.1.11.2 Remove the D-Area Slippers and place them in Shoe Rack.

6.1.11.3 For enter into the Change Room-I put the finger/thumb for scanning on affix biometrics system for authentication. After confirmation through biometrics system green light blow as well as beep sound produce. (This system allows only authorized person entry).

6.1.11.4 Open the Door of Change Room-I by pushing the door with elbow and enter into Change Room-I.

6.1.11.5 Remove the D area Garments and Factory garments and hang them inside the double door Dress Cabinet.

6.1.11.6 Sanitize the hands with 70% IPA Solution.

6.1.11.7 To enter into the Change Room-II, by press the door inter locking button of Change Room-I.

6.1.11.8 Swing cross over bench, open the door by using elbow and enter into the Change Room-II.

6.1.11.9 Sanitize the hands with 70% IPA Solution.

6.1.11.10 Open DGSC and take sterile small gloves & wear it.

6.1.11.11 Keep the Wrappers of gloves in dedicated bin.

6.1.11.12 Take one set of Primary sterile garment and first wear the head cap, upper suit, lower suit and booties.

6.1.11.13 Keep the Empty Dacron bag in dedicated bin.

6.1.11.14 To enter into the Change Room-III, by press the door inter locking button of Change Room-II.

6.1.11.15 Open the door by using elbow and enter into the Change Room-III.

6.1.11.16 Take one Dacron Bag containing one set of Secondary Sterilized Gowns from DGSC.

6.1.11.17 First wear Head Gear followed by Boiler Suit and Booties. Stack the lower portion of Head Gear inside the Boiler Suit.

6.1.11.18 Keep the Empty Dacron bag in dedicated bin.



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6.1.11.19 Wear Sterile Goggles.

6.1.11.20 Take secondary pre sterilized Elbow size gloves & wear it.

6.1.11.21 Keep the Wrappers of gloves in dedicated bin.

6.1.11.22 Check the outfit in mirror for complete gowning.

6.1.11.23 Sanitize the hands with 70% IPA Solution.

6.1.11.24 Press the door inter locking button, Push the Door and enter into Aseptic Area Corridor.

6.1.11.25 For pictorial representation follow **Annexure-XI**.

6.1.12 Exit Procedure for Filtration-Filling Area:

6.1.12.1 Press the push button of door inter locking system and pull the door for enter in Return Change Room–I.

6.1.12.2 Press the push buttons of door inter locking system and pull the door for enter in Return Change Room–II.

6.1.12.3 Press the push buttons of door inter locking system and pull the door for enter in Return Change Room–III.

6.1.12.4 Remove the long/elbow size gloves and keep in respective bin.

6.1.12.5 Remove the aseptic area Goggles and keep them in designated bin.

6.1.12.6 Remove Booties and keep them in the designated bin.

6.1.12.7 Remove the Boiler Suit, Head Gear. Keep them in designated bin.

6.1.12.8 Remove the Primary Garment and keep them in designated bin.

6.1.12.9 Remove the gloves and Keep them in designated bin

6.1.12.10 Open the Double Door Garment Cabinet, Take the D area Garments and Factory garments and wear it.

6.1.12.11 For exit from Change Room-III put the finger/thumb for scanning on biometrics system for authentication. After confirmation through biometrics system green light blow as well as beep sound produce.



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6.1.12.12 Open the Door Change Room-III by pulling the door and enter into D area common corridor.

6.1.12.13 Wear D-Area slippers from shoe rack.

6.1.12.14 For pictorial representation follow **Annexure-XII**.

6.1.12.15 Record the Entry & Exit Details as per **Annexure- XIV**.

Note: 1. During the running Operation in Filtration-Filling Area, If any of gloves gets ruptured, immediate come out from Filtration-Filling Area to Entry change room-IIIrd by using the emergency key., and replace it with new one, Sanitize the hands with IPA 70% v/v Solution and again, Press the door interlocking button of Entry change room-IIIrd, push the door by elbow & enter into in to Aseptic Area Corridor.

2. Use the C-area emergency exit then D-Area emergency exit to skip away, if any type of incident happening in filling-filtration Area.

3. For pictorial representation of Dress Coding System, follow Annexure- XIII.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Entry Procedure for CNC area	
Annexure – II	Exit Procedure for CNC area	
Annexure – III	Entry Procedure for D-grade area	
Annexure – IV	Exit Procedure for D-grade area	
Annexure – V	Entry Procedure for Manufacturing area	
Annexure – VI	Exit Procedure for Manufacturing area	
Annexure – VII	Entry Procedure for Visitors in CNC area	
Annexure – VIII	Exit Procedure for Visitors in CNC area	
Annexure – IX	Entry Procedure for Visitors in D-Grade area	
Annexure – X	Exit Procedure for Visitors in D-Grade area	
Annexure – XI	Entry Procedure for Filtration-Filling area	
Annexure – XII	Exit Procedure for Filtration-Filling area	



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Annexure – XIII	Dress Coding System	
Annexure – XIV	Entry-Exit Record	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

